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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,716	09/21/2001	Grigoriy S. Tchaga	CLON-060	4277

24353 7590 10/21/2003

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,716	TCHAGA, GRIGORIY S.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *20-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the restriction requirement in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search for one of the groups would require a search for the other groups. This is not found persuasive because the groups recite different limitations and thus would require separate search as indicated in the restriction requirement, and furthermore the groups would require separate consideration since each limitation must be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4, 6-12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, 6,482,517.

Anderson discloses the invention substantially as claimed. More specifically, Anderson discloses a method of determining whether a sample includes an analyte of interest, (see column 55, lines 18-22, and column 56, lines 2-4, and lines 65-66), said

method comprising: contacting said sample with an array of a plurality of distinct binding agents (i.e., particles, see column 55, lines 18-22, and lines 66-67, and column 56, lines 2-4, and line 66) displayed on a surface of a solid support (i.e., hydrogel, see column 56, lines 31-32) detecting the presence of any resultant binding complexes on said surface to obtain analyte binding data (see column 55, line 20, and column 56, lines 3-4, and line 66); and employing said analyte binding data to determine whether said sample includes said at least one analyte of interest (see column 55, line 20, and column 56, lines 3-4, and line 66, and column 57, lines 1-3.)

As to claim 2, said sample is contacted with said array in the presence of a metal ion chelating polysaccharide (see column 27, line 1, and column 56, line 65 – column 57, line 3.)

As to claim 3, said metal ion chelating polysaccharide comprises polygalactouronate domains (see column 27, line 1, and column 56, line 65 – column 57, line 3.)

As to claim 4, said metal ion chelating poysaccharide is a pectin (see column 27, line 1, and column 56, line 65 – column 57, line 3.)

As to claim 6, said method further comprises extracting said at least one analyte (i.e., bungarotoxin in column 56, line 50, or alternatively, see column 56, line 65 – column 57, line 3) from a cellular source and labeling (i.e., ^{125}I-labeled, see column 56, line 50) said extracted at least one analyte, wherein said extracting and labeling steps employ the same buffer composition (see column 39, lines 42-47, and column 43, lines 33-35, and column 62, lines 3-7.)

As to claim 7, said buffer composition is free of components that include primary amine moieties (see column 39, lines 42-47, and column 43, lines 33-35, and column 62, lines 3-7.)

As to claim 8, said buffer composition has a pH ranging from about 7 to about 12 (see column 39, line 46.)

As to claim 9, said buffer composition is capable of extracting at least about 95% of the proteins of an initial cellular source (see column 39, line 46.)

As to claim 10, said at least one analyte is a protein (i.e., bungarotoxin, see column 56, line 50.)

As to claim 11, said method comprises determining the presence of at least two distinct analytes (i.e., bungarotoxins, see column 56, line 50) in said sample.

As to claim 12, said method comprises a plurality of washings steps between said contacting and detecting steps (see column 55, line 18, and lines 23-27.)

As to claim 18, said method further comprises a sample fractionating step prior to said contacting step (see column 55, lines 18-22.)

As to claim 19, said fractionating step comprises contacting said sample with at least one affinity column (see column 55, lines 18-22.)

However, Anderson does not disclose that each of said binding agents at least comprises a specific epitope binding domain of an antibody, nor that said method provides a sensitivity of at least 10pg/ml of analyte of interest when said analyte is directly fluorescently labeled.

Anderson however does disclose that receptor proteins are disposed in the internal core of the particles (see column 55, lines 66-67.) It would have been obvious to one of ordinary skill in the art to utilize a specific epitope binding domain of an antibody as the receptor protein since it is well known that receptor proteins encompasses a specific epitope binding domain of an antibody, and moreover, Anderson teaches that an antibody can be incorporated in the particle (see column 49, lines 62-65.)

Furthermore, although Anderson does not specifically disclose that the method provides a sensitivity of at least 10pg/ml of analyte of interest when the analyte is directly fluorescently labeled, it would have been obvious that the invention can provide the sensitivity as claimed since the invention provides a large improvement in stability of the particles over the prior art (see column 56, lines 65-67.)

2. Claims 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, 6,482,517, in view of Levy et al., 5,635,609.

Anderson teaches the invention substantially as claimed, see above, except for the pectin being specifically apple pectin.

Anderson teaches that the particle comprises a surfactant such as pectin, see column 26, line 46, and column 27, line 1.

Levy et al. likewise teach formation of diagnostic particles (i.e., spheres, see column 1, lines 22-24, lines 8-12, and lines 27-31) including formation of a stable membrane (see column 1, lines 38-47), using esterified polysaccharide that is capable

of gelling in the presence of cations (see column 4, lines 6-9), such esterified polysaccharide being for example, pectin (see column 4, line 9), and in particular, apple pectin (see column 18, lines 23-25.)

It would have been obvious to use apple pectin as the specific pectin used in the formation of the Anderson diagnostic particles, since apple pectin is a known pectin used in formation of diagnostic particles, as taught by Levy et al., and has the additional advantage of being capable of gelling in the presence of cations.

3. Claims 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, 6,482,517, in view of Jackowski, 5,747,274.

Anderson teaches the invention substantially as claimed, see above, except for the method comprising the step of quantitatively detecting at least two different protein analytes in said sample. (As to claim 17, said method is a method of determining a protein expression profile for said sample see column 55, lines 66-67, and column 56, lines 50-66.) Moreover, Anderson does teach that the invention can be applied in biochemical assays which are important in clinical diagnosis, (see column 56, line 65 – column 57, line 3.)

Jackowski discloses a method and device for diagnosing chest pain, wherein the assay method and device includes detection of at least two different protein analytes in the sample, see column 24, line 50 – column 25, line 9, and claim 1, for example.)

Thus, it would have been obvious to one of ordinary skill in the art to use the Anderson method to quantitatively detect at least two different protein analytes in said sample to obtain additional data for diagnostic purposes, as taught by Jackowski.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kuhn et al., 5,773,227, disclose use of polysaccharides conjugated to both a chelating group suitable for the selective complexation of metal cations, and a targeting peptide specific for a cellular substructure. Kuhn et al. also teaches that the chelating compound can incorporate a fluorescent or fluorogenic moiety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
10/20/03